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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,786	06/26/2002	Jerome Pierrard	022701-966	1914

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EXAMINER	
WAX, ROBERT A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,786	PIERRARD ET AL.	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *17-19* is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12212001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. The current application filed on June 26, 2002 is a 371 of PCT/FR00/01725 filed on June 21, 2000, which in turn claims priority to French application 9907963 filed on June 22, 1999.

Information Disclosure Statement

2. The information disclosure statement filed December 21, 2001 has been considered. Please see the attached initialed PTO-1449.

Claim Rejections - 35 USC § 112, Second Paragraph

3. Claims 1, 7, 8-12, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At the outset, examiner points out that the claims under examination are claims 2-19 from the Preliminary Amendment filed June 26, 2002 and claim 1 is the version of claim 1 amended in the PCT, during Chapter II.

Claim 1 contains the language, "foreign to its natural genetic inheritance" which is very unusual. Examiner suggest the phrase from the specification, page 5, line 12, "which is not a natural element of the genome of the strain" as replacement language.

Claims 7 and 10 recite, "and it conserves the ability"; examiner suggests amendment to read, "and wherein the strain conserves the ability".

Claims 7 and 8 recite, "[T]he *Xanthomonas* strain as claimed in claim 1" but there is insufficient antecedent basis for this limitation in the claims since claim 1 is not limited to *Xanthomonas*.

Claims 11 and 12 do not recite the language, "conserves the ability to produce exopolysaccharide." The whole thrust of the invention is the removal of the phytopathogenic activity while retaining the exopolysaccharide producing capability. Failure to recite this in the claim therefore constitutes failure to "claim the subject matter which applicant regards as the invention".

Claim 14 is drawn to a method wherein the sole step is "using". While this is not a so-called "use" claim, the lack of steps of the method renders it indefinite.

Claims 9, 15 and 16 are included in this rejection because they depend from claims 8, 7 and 1, respectively, and fail to cure the defect of the base claim.

Examiner wishes to note for the record that the term, "essentially nonphytopathogenic" is not indefinite because a limiting definition is provided at page 8, lines 15-20 of the specification.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

4. Claims 1-6, 8, 9, 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification clearly establishes that the inventors had possession of *Xanthomonas campestris* strains that have been made nonphytopathogenic while retaining the ability to produce exopolysaccharide by deletion or alteration of the *hrp* or *hrc* genes without the addition of DNA foreign to the strain's genome. Applicants are not in possession, however, of all phytopathogenic bacterial strains that have been made nonphytopathogenic by deletion or alteration of just any, nonspecified, virulence gene with or without the addition of DNA foreign to the strain's genome.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original).

Just as the claims at issue in *UC v. Lilly* defined the invention by the function of the claimed DNA (encoding insulin), the instant claims define the claimed bacterial

strains only by their functional properties. The court held this sort of functional definition insufficient. "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *UC v. Lilly*, at *24-*25.

The instant claims lack adequate written description under *UC v. Lilly* because the strains are defined only by the loss of phytopathogenic nature by inactivation of a virulence gene, however, the structural characteristics of the virulence genes (other than *hrp* and *hrc*) are not disclosed.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

5. Claims 1-6, 8, 9, 13 and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *Xanthomonas campestris* strains that have been made nonphytopathogenic while retaining the ability to produce exopolysaccharide by deletion or alteration of the *hrp* or *hrc* genes without the addition of DNA foreign to the strain's genome, does not reasonably provide enablement for all phytopathogenic bacterial strains that have been made nonphytopathogenic by deletion or alteration of just any, nonspecifed, virulence gene with or without the addition of DNA foreign to the strain's genome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in

determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In the instant case, (1) the amount of experimentation is large because of the large number of phytopathogenic bacteria and the indeterminate number of virulence genes, as well as the many ways the virulence genes could be inactivated; (2) the amount of guidance provided by the specification is limited to inactivation of *hrp* and *hrc* genes in *Xanthomonas campestris* strains since no correlation is shown between *X. campestris* and other phytopathogenic bacteria. Continuing, (3) the working examples shown in the specification is *hrpA1-C2* deletion in *Xanthomonas campestris* strain RPA-BIOCAT826; As for the next Wands factor, (4) the nature of the invention is *Xanthomonas campestris* strains that have been made nonphytopathogenic while retaining the ability to produce exopolysaccharide by deletion or alteration of the *hrp* or *hrc* genes without the addition of DNA foreign to the strain's genome.

The prior art (5) shows a *Xanthomonas campestris* strain that was made nonphytopathogenic by insertion of "a transposon that allows transcriptional fusions to a promoterless luciferase (*lux*) operon" (Kamoun et al., page 5165, second paragraph); (6) the relative level of skill in this art is very high; (7) the predictability of the art is limited. Page 7 of the instant specification states that the inventors were surprised by the fact that a bacterium which has become stably nonphytopathogenic, by deletion of a

fragment of considerable size which affects several kilobases of genes involved in virulence is, however, capable of producing xanthan gum in an amount and a quality in all respects comparable to that produced by the wild-type strain from which the construct was produced. This indicates that those of ordinary skill in the art would expect that, if one were to delete several kilobases worth of DNA to remove one function, that other functions would be similarly affected. Thus, the predictability that exopolysaccharide production would be maintained if virulence were removed is low. Finally, (8) the claims are fairly broad in view of the large number of phytopathogenic bacteria; the large number of virulence genes and the many ways the virulence genes could be inactivated.

Based on this analysis, the conclusion that it would require undue experimentation to practice the instant invention is inescapable.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement, Deposit of Biological Material

6. Applicants' referral to the deposit of the RPA-5 BIOCAT1016, 1017, 1019 and 1021 strains on pages 12 and 13 of the specification is an insufficient assurance that all of the conditions of 37 CFR §§ 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by

an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

Conclusion

7. Claims 17-19 are allowed. A search for the claimed sequences resulted in a finding that the prior art does not teach them. Claims 1-16 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Wax
Primary Examiner
Art Unit 1653

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